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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,115

11/14/2005

Trevor Morgan

9013-71

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EXAMINER

TSAY, MARSHA M

ART UNIT

PAPER NUMBER

1656

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,115	<b>Applicant(s)</b> MORGAN ET AL.	
	<b>Examiner</b> Marsha M. Tsay	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6,8 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8 and 10-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/02/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 2, 2008 has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 2, 7, 9 are canceled. Claims 1, 3-6, 8, 10-21 are pending and currently under examination.

Priority: The priority date is February 21, 2003.

## **Objections and Rejections**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

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Claim 1 has been amended to include the limitation, wherein the film is in a form other than that of an extruded tubular casing. There does not appear to be support for this limitation in the original specification, and therefore, this constitutes as a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 3-4, recite a fat content in the film which is reduced to a level below 20% on a dry weight basis. Since there is no lower limit, the fat content in the film can be reduced to 0%. However, claim 1 line 5 recites a ratio by weight of collagen to fat in the film is at least 2.5:1. Therefore, further clarification is requested regarding the fat content that is present or not present in the film.

Similarly claim 3 recites the fat content in the film is reduced below 18% by weight on a dry weight basis, which can include 0%. Claim 3 is dependent on claim 1, which recites a ratio by weight of collagen to fat in the film is at least 2.5:1.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3-6, 8, 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. (US 20050031741; previously cited) in view of Eckmayer et al. (US 6482240; IDS, previously cited). Morgan et al. teach collagen casings or film made from an extrudable collagen gel, wherein the collagen is porcine collagen (p. 1 [0001]-[0002]). In working examples 3-4, Morgan et al. teach a porcine collagen film was prepared from an extrudable porcine collagen gel, having a weight ratio of collagen to fat of around 30:1 (p. 4 [0059]; claims 1, 4-6, 17). The table in paragraph [0062]) indicates a fat percentage of 0.31% and 0.19% for examples 3 and 4, respectively (p. 4; claims 1-3). The porcine collagen casing in example 20 comprises 6.0% of caprine (goat) collagen on a dry weight basis (p. 12; claims 7-8). Morgan et al. also teach that the collagen properties of the casings can be varied by mixing collagen derived from young pigs (4 mos. old) and older pigs (3 yrs. old) in ratios of 0:100 to 100:0 (p. 2 [0019]; claim 9). In example 12, Morgan et al. teach a porcine collagen casing with a humectant (i.e. glycerol) level of 21.5% on a dry weight basis (p. 8-9; claims 13-14). The collagen casing in example 16 comprises propylene glycol alginate (p. 10; claims 10-12). In example 9, Morgan et al. teach the porcine casing further comprises glutaraldehyde (p. 6 [0128]; claim 15). Also, the collagen casing has a collagen solids content of 7% (p. 13-14; claim 16). In example 1-4, Morgan et al. teach the porcine collagen casings were used to make sausages (p. 3-4; claim 21). The casing of Morgan et al. can also be used to make edible string and/or netting (p. 2 [0022]; claim 18). Further, Morgan et al. teach a method of producing an extruded porcine collagen film from sow collagen comprising soaking sow skins, removing fat by a fleshing machine (p. 3 [0032]), forming an extrudable gel from the sow skins by blending and disintegrating porcine

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skin (p. 3 [0039]), and extruding the gel to form a casing (p. 3 [0040]-[0045]) (claims 19-20).

Morgan et al. do not explicitly teach the collagen casing is in another film besides a tube.

Eckmayer et al. teach collagen membranes formed from porcine skins are enzymatically defatted, ground into a gel-like mass, extruded and dried into a collagen membrane (col. 2 lines 59-67). Eckmayer et al. teach the collagen membranes can be formulated as films (col. 1 lines 13). In example 1, Eckmayer et al. teach a method of producing a porcine collagen film comprising defatting porcine skins by mechanical means (col. 4 line 64), forming a gel-like fluid mass (col. 8 lines 17), and extruding the gel to form a film and/or membrane (col. 10 line 1). Eckmayer et al. teach the collagen film can be used as a net to wrap around ham (col. 12 lines 16-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Morgan et al. by extruding the collagen gel to form a film as suggested by Eckmayer et al. instead of as a thin-walled tube (claims 1, 3-6, 8, 10-21). The motivation to do is given by Eckmayer et al., which disclose that collagen membranes can be extruded from collagen gels and formed into a film to wrap around a food product. It would be reasonable for one of ordinary skill to recognize that a collagen membrane formed into a film can have broader applications than a collagen membrane formed into a tube shape, i.e. casing.

Although Morgan et al. or Eckmayer et al. do not specifically disclose the limitation of a wet tear strength greater than 300 gf/mm, it would be reasonable for one of ordinary skill to recognize that this property would be present in the collagen product of Morgan et al. in view of Eckmayer et al. since Morgan et al. disclose an extruded porcine collagen product that meets the limitations of instant claim 1 (claim 17).

The previous 102(b) and 102(e) rejections by Eckmayer et al. and Morgan et al. have been withdrawn. However, the references are still believed to be relevant art under 103(a).

Applicants assert that Eckmayer et al. do not teach ratios as presently defined in claim 1. This has been remedied by the Morgan et al. reference.

Applicants further assert that the terms “film” and “casing” do not overlap and have distinct meanings to one of skill in the industry. Applicants assert Morgan et al. do not use the terms “film” and "casing" interchangeably. This has been remedied by the Eckmayer et al. reference.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

June 16, 2008